## REMARKS

Claims 1-28 are pending in the application. Claims 1, 2, 12, 14, and 20 are amended herein. Claim 19 is canceled herein.

**Claim Objections**

Claims 1, 14, and 19 are objected to by the Examiner because of the positive recitation of a human being and/or human anatomy as an element of the claimed combination. Claims 1 and 14 have been corrected as suggested by the Examiner. Claim 19 has been canceled.

**Claim Rejections Under 35 USC § 103**

Claims 1, 2, 14, 17, 19, and 20 are rejected as being obvious over Berggren et al in view of Frank et al.

Berggren et al disclose the use of aerosolized surfactant with CPAP (continuous positive airway pressure) in the treatment of neonatal respiratory distress syndrome. The surfactant aerosol is generated from a dilute Cerosurf® solution with a jet nebulizer, and administered via nasal CPAP equipment into the nostrils of the infant according to normal clinical routines. (page 461, col. 1). Fig. 1 of Berggren et al discloses a wiring diagram of the CPAP system showing the various components of the CPAP system used. It appears from Fig. 1 that a first circuit is provided to supply $O_2$-air (through a heater/humidifier) to a nasal mask and a second circuit is provided to supply a carrier gas under pressure (regulated by a pressure regulator) to a nebulizer. The driving pressure in the nebulizer generates surfactant aerosol that is carried by a circuit to the nasal mask. The Examiner states in the Office Action that the conduit between the humidifier and the nasal mask is a "respiratory circuit" for providing gas communication between the pressure-generating circuit and the nasal mask. If so, Berggren et al do not teach a nebulizer coupled to the respiratory circuit, as required by claim 1. As clearly shown in Fig. 1, the nebulizer is coupled to the nasal mask, not the "respiratory circuit".

Furthermore, the Examiner states in the following sentences that Berggren et al do not expressly disclose a pressure-generating circuit at all. The Examiner cites Frank et al as teaching a pressure-generating circuit in a CPAP system, and contends that it would have been

obvious to modify Berggren et al to include the pressure-generating circuit of Frank et al. Applicants submit that the pressure-generating circuit of Frank et al is analogous to the first circuit shown in Fig. 1 of Berggren et al. In addition, Frank et al teach a conduit (54) (Fig. 4) that provides gas communication between the pressure-generating circuit (pressure/flow generating system (48)) and a patient interface device (56), and therefore may be considered a "respiratory circuit". Although both Berggren et al (Fig. 1) and Frank et al (col. 4, lines 45-46) suggest that a nebulizer may be connected to the CPAP system, there is no teaching in either reference that the nebulizer is coupled to the respiratory circuit. Accordingly, there is no motivation or suggestion in the references themselves to couple a nebulizer with a respiratory circuit of a CPAP system, as required by claim 1.

With respect to the rejection of claim 20, which requires that the pressure-generating circuit have a higher volume flow of gas than the respiratory circuit, Frank et al teach a first conduit connecting a gas flow generator (60) to a pressure-regulating device (64) to provide a first high-volume gas flow and a second gas conduit (54) from pressure/flow generating system (48) to a patient interface device (56) for providing a second gas flow (50). The second gas flow of Frank et al could be lower volume than the first gas flow, e.g. as the result of being regulated by pressure/flow controller (64). However, as explained in connection with the rejection of claim 1, there is no teaching or suggestion in Berggren et al/Frank et al that the nebulizer is coupled to the second conduit (the respiratory circuit) containing the lower volume flow, as expressly required by claim 20. Applicants contend that the Examiner's conclusion of obviousness is based on knowledge gleaned from Applicant's own disclosure that it is beneficial to couple the nebulizer to the lower volume flow of gas in the respiratory circuit, combined with the exercise of impermissible hindsight.

Claim 2 has been amended to expressly state that the respiratory circuit is connected to the pressure-generating circuit at a location between the flow generator and the pressure-regulating device. This limitation clearly precludes conduit 54 of Frank et al, which is located downstream of the pressure regulating device (see Fig. 4). It is also clear that the respiratory circuit taught by Berggren et al is not located between a flow generator and a pressure-regulating device.

Claim 14, and claim 17 dependent thereon, have been amended to specifically describe a junction unit disposed in the first gas conduit between the flow generator and the pressure regulating device, wherein the junction unit comprises a primary gas conduit to accommodate the first gas flow and a branch gas conduit that diverts a portion of the first gas flow into the second gas conduit to provide the second lower gas flow. This limitation clearly distinguishes over Frank et al which does not teach or suggest the junction unit or the diversion of the first gas flow to provide the second lower gas flow. Frank et al teach that any possible lower gas flow 50 between pressure/flow generating system 48 and patient interface device 56 is as the result of using pressure/flow controller 64 to reduce the high-pressure gas flow from pressure/flow generator 64 to a lower pressure gas flow 50 in conduit 54 . This reduction in gas pressure accomplishes the ramp function provided by system 48 (see col. 8, lines 21-34). Claim 14 has been further amended to expressly state that the nebulizer is coupled to the respiratory circuit so as to emit aerosol into a lower volume second gas flow in the respiratory circuit. All of the foregoing amendments are fully supported by the specification and do not constitute new matter.

As described in the specification (e.g. page 4, paragraph [0010]), the system and method of the present invention minimizes the dilution effect that would occur if the aerosol is introduced into the high flow of gas passing through the pressure-generating circuit. For example, Berggren et al speculate that their failure to document any beneficial effects of aerosolized surfactant in a CPAP system was due to excessive loss of aerosolized material in the particular conventional CPAP device that was used (page 463, first column, lines 27-30). Although Berggren et al demonstrate the need to improve the efficiency of CPAP systems using aerosol, there is no suggestion or motivation in Berggren et al, alone or in combination with Frank et al, to create a second lower volume gas flow and to introduce the aerosol into that gas flow.

Claims 3, 4, 15, and 16 are rejected as being obvious over Berggren et al in view of Frank et al, as set forth above, further in view of Fink et al. Claims 3 and 4 (which are ultimately dependent on amended claim 1), and claims 15 and 16 (which are ultimately dependent on claim 14) are not obvious over Berggren et al in view of Frank et al for the reasons

described above in connection with the rejection of claims 1 and 14. The disclosure of Fink et al that the circuits of a pressure-generating system may comprise flexible (corrugated) tubing of different diameters adds nothing to the disclosure of Berggren et al as modified by Frank et al that teaches or suggests all of the limitations of amended claims 1 and 14.

Claims 5-10, 18, and 21-28 are rejected as being obvious over Berggren et al in view of Frank et al, as set forth above, further in view of Davison. Claims 5-10 (which are ultimately dependent on claim 1), claim 18 (which is ultimately dependent on claim 14) and claims 21-28 (which are ultimately dependent on claim 20) are not obvious over Berggren et al in view of Frank et al for the reasons described above in connection with the rejection of claims 1, 14 and 20. Davison teaches a vibrating aperture-type aerosol generator (annular member 4 supporting a membrane 6 for vibration by actuation of transducer 10) that dispenses a aerosol into the air flow in a duct 32 communicating between an air inlet 33 and an inhalation port 34 suitable for oral inhalation. There is no teaching or suggestion in Davison that duct 32 is a respiratory circuit as defined by amended claims 1, 14 and 20. In addition, Davison adds nothing to the disclosure of Berggren et al as modified by Frank et al that teaches or suggests all of the other limitations of amended claims 1, 14 and 20.

Claims 11-13 are rejected as being obvious over Berggren et al in view of Frank et al, as set forth above, further in view of Duarte et al. Claims 11-13 (which are ultimately dependent on claim 1) are not obvious over Berggren et al in view of Frank et al for the reasons described above in connection with the rejection of claim 1. Duarte et al teach a nebulizer located in the direct vicinity (within 30 cm) of an artificial airway (an endotracheal tube) for the purpose of improving aerosol delivery. Duarte et al add nothing to the disclosure of Berggren et al as modified by Frank et al that teaches or suggests all of the other limitations of amended claim 1. Claim 12 has been amended to specify that the nebulizer is an integral part of the patient interface device. This limitation further distinguishes over Berggren et al wherein the nebulizer is shown in Fig. 1 as being a separate element of the CPAP system, apart from the nasal mask.

For the reasons set forth above, withdrawal of the rejections are respectfully requested.

**Statement of Common Ownership**

The present application Ser. No. 10/828,765 and co-pending Application Ser. Nos. 10/883,115; 10/957,321; and 11/080,279 (incorrectly identified as 10/080,279 in the Office Action) were, at the time the invention was made, both owned by Aerogen, Inc., predecessor-in-interest to current owner Nektar Therapeutics.

**Double Patenting Rejection**

Claims 1-28 are provisionally rejected for nonstatutory obviousness-type double patenting over claims 1-28 of co-pending Application Ser. No. 10/883,115; claims 1-25 of co-pending Application Ser. No. 10/957,321; and claims 1-25 of Application Ser. No. 11/080,279 (incorrectly identified as 10/080,279 in the Office Action). Terminal disclaimers in compliance with 37 CFR 1.321(c) are filed herewith. Since the present application and aforementioned co-pending applications are shown to be commonly owned (see Statement of Common Ownership above), it is respectfully submitted that this terminal disclaimer overcomes the rejection. Withdrawal of the rejection is respectfully requested.

**Prior Art Cited in a Related Application**

Claims 1-28 of International Application No. PCT/US2005/013488, filed April 20, 2005 are identical to the original claims 1-28 of the present application. A Supplemental Information Disclosure Statement (IDS) is filed concurrently herewith that calls attention of the Examiner to new prior art references cited in the International Search Report. A copy of the Written Opinion of the International Searching Authority with regard to the novelty, inventive step and industrial applicability of claims corresponding to claims 1-25 of the present application is also attached. As stated in the IDS, it is respectfully requested that the Examiner consider these references during the prosecution of the current application, and make these references of record herein.

## CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,

Mart C. Matthews
Reg. No. 26,201

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 303-571-4000
Fax: 415-576-0300
MCM/cl
60798768 v1